Decision Memo for Cardiac Pacemakers (CAG-00063R2)

Decision Summary

CMS will revise CIM65-6 to focus the instruction on the indications for pacemaker use rather than on the pacemaker implantation procedure. This reflects our finding that pacemaker implantation is no longer an experimental procedure. The revised provisions will focus on the medical conditions that indicate that cardiac pacing is a reasonable and necessary treatment. In this decision memorandum, we change only this framework of the coverage determination and do not review the specific provisions setting forth conditions that indicate that cardiac pacing is reasonable and necessary.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue an NCD. Though the policy is effective with publication of this decision, CMS must issue a manual instruction, program memorandum, CMS ruling or Federal Register Notice, giving specific directions to our claims processing contractors. That issuance is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual.

To: Administrative File: CAG 00063R2
Cardiac Pacemakers

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Subject: Coverage Decision Memorandum for Cardiac Pacemakers
Date: March 12, 2004

I. Decision

CMS will revise CIM65-6 to focus the instruction on the indications for pacemaker use rather than on the pacemaker implantation procedure. This reflects our finding that pacemaker implantation is no longer an experimental procedure. The revised provisions will focus on the medical conditions that indicate that cardiac pacing is a reasonable and necessary treatment. In this decision memorandum, we change only this framework of the coverage determination and do not review the specific provisions setting forth conditions that indicate that cardiac pacing is reasonable and necessary.

II. Background

Cardiac Pacemakers

Cardiac pacemakers are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate and/or rhythm. Without treatment, an abnormal heart rate can lead to weakness, confusion, dizziness, fainting, shortness of breath, and death. Pacemakers are generally used for persistent, symptomatic second- or third-degree AV block and symptomatic sinus bradycardia. For some patients, it may be appropriate to implant a pacemaker in order to continue pharmacological treatment.[1] It is essential to document an association between symptoms and the dysrhythmia before pacemaker implantation.

The implantation procedure is typically performed under local anesthesia and requires only a brief hospitalization. A catheter is inserted into the chest and the pacemaker's leads are threaded through the catheter to the appropriate chamber(s) of the heart. The surgeon then makes a small "pocket" in the pad of flesh under the skin on the upper portion of the chest wall to hold the power source. The pocket is then closed with stitches. The procedure leaves a small scar and the battery can be felt through the skin.

Cardiac pacemakers are commonly accepted by the medical community as reasonable and necessary to treat many serious medical conditions.[2] There are some uses, however, that require considerable expertise and judgment and may not be supported by substantial scientific evidence, and therefore are not as commonly accepted. This distinction is already set forth in CIM-65-6 and we do not review the particular uses in this decision memorandum.

III. History of Medicare Coverage

Initial Coverage Request

Medicare's national coverage decision (NCD) for cardiac pacemakers can be found at CIM 65-6. It was last updated in 1985, and limits the number of conditions for which CMS will pay for implantation of a cardiac pacemaker.

In June 2000, Medtronic requested that CMS review the use of a cardiac pacemaker to treat asymptomatic bradycardia in post-MI patients about to initiate long-term ß-blocker drug therapy. After a complete systematic review of the evidence provided, CMS posted a coverage decision memorandum (CAG-00063N) on March 20, 2001, that maintained its current non-coverage NCD that pacemaker implantation would not be considered reasonable and necessary in these patients.

Reconsiderations

Medtronic Inc. (Medtronic) and Dr. Jeffery J. Goldberger of Northwestern University each requested reconsideration of CAG-00063N. We accepted these requests as a single reconsideration. A number of concerns about the CMS analysis in this NCA were raised in the letters submitted by Medtronic and Dr. Goldberger, dated April 3 and April 4, 2001 respectively, (which we accepted as a single reconsideration). These concerns are delineated in CAG00063R. Medicare maintained its policy to not cover pacemaker implantation for post-MI patients with asymptomatic bradycardia.

On October 24, 2003, CMS began a national coverage determination reconsideration process for cardiac pacemaker. The present language speaks to "the medical necessity, or lack thereof, for pacemaker implantation..." The current reconsideration is to determine whether CMS should revise the current NCD to remove pacemaker implantation as the technology for which a reasonable and necessary determination should be made. In order to appropriately assess the benefits of various pacemakers for a number of old and new indications, it is necessary to separate "implantation" from clinical use of a pacemaker in making reasonable and necessary determinations.

IV. Timeline of Recent Activities

October 24, 2003	CMS opens an NCD and requests public comment on the appropriateness of removing implantation of pacemakers as the technology for which a reasonable and necessary determination should be made.

V. FDA Status

The FDA status for pacemakers can be reviewed in CAG 00063N.

VI. Evidence

The purpose of this NCD is to determine the appropriateness of removing implantation of pacemakers as the issue for which a reasonable and necessary determination is made for use of cardiac pacing.

Pacemaker implantation is described above. Less than 2% of patients suffer from complications due to pacemaker implantation. Examples of complications that may occur as a result of pacemaker implantation are not radically different from those that occur with other catheterization procedures, e.g., bleeding, punctured vein, infection, or collapsed lung.[3]

Professional Society Position Statements

The American College of Cardiology and NASPE - Heart Rhythm Society submitted a joint-letter in support of CMS' proposed action.

Public Comment

CMS received five letters in support of the proposed action.

VII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

As noted in the Background section above, the procedure used to implant the cardiac pacing devices is neither experimental nor routinely harmful. The technique for implantation of these devices has remained essentially the same since their initial deployment. The risk of harm from implantation of cardiac pacing devices is known and minimal.[4] Therefore, the coverage provisions set forth in CIM65-6should be revised to focus on whether cardiac pacing is a reasonable and necessary treatment for particular medical conditions, rather than on the risks of pacemaker implantation.

We are not currently reviewing the conditions listed in current coverage provisions as indications that cardiac pacing is reasonable and necessary. We believe that those coverage provisions identify indications that cardiac pacing is reasonable and necessary and are flexible in permitting carrier discretion to address the particular circumstances in each case. We recognize that new uses for cardiac pacing have been developed in recent years. Many of these new uses have not been rigorously studied or conclusive evidence regarding the long-term benefit of pacing to new classes of patients is lacking. We intend to continue to assess the benefits of various pacemakers for a number of new indications, and in some circumstances, we might also address currently covered indications if new evidence indicates harm or lack of benefit. But at this time, we are taking the more limited step of revising CIM 65-6 to make clear that the focus of the determination of whether cardiac pacing is reasonable and necessary is not the surgical implantation procedure itself, but instead is based on the medical indications that justify the use of cardiac pacing.

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1 Bennett, J. Claude, Goldman, Lee. Cecil Textbook of Medicine. 2000; 1: 249.

2 Silverman BG, Gross TP, Kaczmareki, Hamilton P and Hamburger. The epidemiology of pacemaker implantation in the United States. *Public Health Reports* 1995;110(1):42-46 and Daley WR, Kaczmarek RG. The epidemiology of cardiac pacemakers in the older US population. *Journal of the American Geriatrics Society* 1998;46(8):1016-1019.

3 See Cardiac Pacemaker Decision Memorandum (CAG 00063N) and Pavia S, Wildoff B. The management of surgical complications of pacemaker and implantable cardioverter-defibrillators. *Current Opinion in Cardiology* 2001;16(1):66-71.

4 Yamamura KH, Kloosterman EM, Alba J et al. Analysis of charges and complications of permanent pacemaker implantation in the cardiac catheterization laboratory versus the operating room. *Pacing and Clinical Electrophysiology* 1999;22(12):1820-1824.

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